SAPIEN 3心臓弁の30日合併症率は低い (Abstract 404-14)

PARTNER II S3：第三世代TAVRシステムは死亡率、脳卒中および弁周囲逆流発現率が低い

PARTNER II S3: Third generation TAVR system associated with low mortality, stroke and paravalvular regurgitation

SAPIEN 3心臓弁は死亡、脳卒中および弁周囲逆流発現率が旧世代の人工弁よりも手術の高リスク患者において低く、また中等度リスク患者においても有望な結果を示した、との研究結果が第64回American College of Cardiology学会で発表された。PARTNER II S3トライアルでは、施術中に使用するバルーン拡張システムが最新の改良版であるSAPIEN 3弁を用いた経カテーテル大動脈弁置換術（TAVR）の30日間の転帰を評価した。高リスクまたは手術不能なスタディ対象患者583人に加え、中等度リスク患者1076人がこの新しいデバイスを用いて治療を受けた。30日間死亡率は極端に低く、脳卒中発症率は両群ともに約1%であり有意な弁周囲逆流は稀であった。死亡率は高リスク群で2.2%であり、中等度リスク群で1.1%であった。高リスク群の死亡率の1.4%および中等度リスク群の死亡率の0.9%が心臓関連死であった。高リスク患者の脳卒中率は1.5%であり、うち0.9%は身体障害の状態であった。中等度リスク群におけるこれらの割合はそれぞれ2.6%および1%であった。研究者らは、これらの結果は30日間のデータでありさらに長期の追跡が必要であると強調している。

Full Text

The SAPIEN 3 heart valve demonstrated lower death, stroke and paravalvular leak rates than earlier generation devices in patients at high risk for surgery and showed encouraging results in intermediate-risk patients, according to research presented at the American College of Cardiology's 64th Annual Scientific Session.

Transcatheter aortic valve replacement (TAVR) is approved for patients with severe aortic stenosis whose health profile makes them ineligible or high-risk candidates for surgery. This trial, called PARTNER II S3, evaluated 30-day outcomes with the SAPIEN 3 valve, the latest modification of the balloon-expandable system used in these procedures. This is the first presentation of large-scale data for the third-generation device and the first report of outcomes in intermediate-risk patients in the United States.

In addition to the study's 583 high-risk or inoperable patients, 1,076 intermediate-risk patients were treated with the new device. The death rate was 2.2 percent, or 13 patients, in the high-risk group and 1.1 percent, or 12 deaths, in the intermediate-risk group. Heart-related deaths accounted for 1.4 percent of the mortality in the high-risk group and 0.9 percent in the intermediate-risk group. High-risk patients had a stroke rate of 1.5 percent, 0.9 percent of them disabling; in the intermediate-risk group, those rates were 2.6 percent and 1 percent, respectively.

"The 30-day mortality rates were extremely low, stroke rates were approximately 1 percent in both groups and significant paravalvular regurgitation was rare," said Susheel Kodali, M.D., director of the Heart Valve Center, Columbia University Medical Center/New York-Presbyterian Hospital, New York City, and a co-principal investigator of the study. "Death and stroke rates have been decreasing with every modification of the SAPIEN system."

Major vascular complications occurred in about 5 percent of high- and intermediate-risk patients, a reduction of two-thirds compared with the first-generation SAPIEN system. Other clinical events also were reduced from results in previous SAPIEN studies, including myocardial infarction in 0.5 percent of patients, injury to the aortic area called annular rupture in 0.3 percent and coronary obstruction in 0.3 percent. A new permanent pacemaker was implanted in 13 percent of high-risk patients and 10 percent of intermediate-risk patients, a slightly higher rate than with earlier balloon-expandable valves.

Paravalvular leak has been associated with poorer outcomes after TAVR. The third-generation model used in this study was modified with an outer skirt designed to reduce leak by sealing gaps around the valve. With the new device, 3.7 percent of patients had moderate leak and 0.1 percent had severe leak. By comparison, currently approved devices have rates of moderate or severe paravalvular leak in the range of 10 to 20 percent.

Other alterations allow the valve to be delivered with a smaller catheter, increasing the percentage of procedures that can be performed via the femoral artery, a route preferred because of better outcomes. When transfemoral delivery is not possible, the route is generally through the ribs.

"For the first SAPIEN devices, we were able to use the less invasive transfemoral approach in about 60 percent of patients," Kodali said. "For SAPIEN 3, more than 90 percent of procedures can be transfemoral."

One-year data for high-risk patients with the new device will be available later in 2015. Longer-term outcomes for the intermediate-risk patients treated with the new device will be compared with the intermediate-risk surgical patients in the PARTNER IIA trial once the two-year endpoint is reached. Patients will be followed for five years.

"We needed to see if we've solved the valve leakage issue before we move to lower-risk patients," Kodali said. "Although we have to wait for longer-term data, what we've seen thus far makes us excited about those data and what they'll show."

Kodali emphasized that these are 30-day data and that longer-term follow up is required.

Edwards Lifesciences sponsored the trial. The hospital conducts training programs for the company, and Kodali receives compensation from the company for travel related to the trial.

Special note: Michael Davidson, a surgeon from Boston and one of the original PARTNER clinical trial investigators, was killed in January at the age of 44 by the son of a former patient. ACC and the PARTNER trial team dedicate this presentation and journal paper to his memory.

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